

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				<i>Application Number</i>	10/575,132
				<i>Filing Date</i>	July 7, 2006
				<i>First Named Inventor</i>	Sarah Donald
				<i>Art Unit</i>	1612
				<i>Examiner Name</i>	Chris E. Simmons
<i>(Use as many sheets as necessary)</i>				<i>Attorney Docket Number</i>	13566.105014
Sheet	1	of	3		

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Signature	/Chris Simmons/	Date Considered	05/17/2009
-----------------------	-----------------	--------------------	------------

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST).¹ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.² Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.³ Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/575,132
(Use as many sheets as necessary)				Filing Date	July 7, 2006
				First Named Inventor	Sarah Donald
				Art Unit	1612
				Examiner Name	Chris E. Simmons
Sheet	2	of	3	Attorney Docket Number	13566.105014

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
		Alexopoulos, "Phase II study of pegylated liposomal doxorubicin (Caelyx(R)) and docetaxel as first-line treatment in metastatic breast cancer," Ann. Oncol., 2004, 15(6):891-5			
		D'Incalci et al., "Unique Features of the Mode of Action of ET-743", The Oncologist, 7, p. 210-216, June 2002			
		Donald et al, "Comparison of four modulators of drug metabolism as protectants against the hepatotoxicity of the novel antitumor drug yondelis (ET-743) in the female rat and in hepatocytes in vitro," Cancer Chemother Pharmacol, April 2004, vol. 53, pp. 305-12			
		European Medicines Agency (EMEA), "Scientific Discussion" from the European Public Assessment Report for Yondelis®, Revision 1, published March 31, 2008, downloaded from the internet on April 2, 2008, from the website << http://www.emea.europa.eu/humandocs/Humans/EPAR/yondelis/yondelis.htm >>			
		Forouzesh et al., Proc. Am. Soc. Clin. Oncol. ASCO meeting, Abstract 373, June 3, 2001, Internet Archive Entry from the website << http://web.archive.org/web/*/ http://www.asco.org/ >>, 32 pages			
		Gourley C. et al., "Malignant mixed Mesodermal Tumours - Biology and Clinical Aspects," European Journal of Cancer, 2002, vol. 38, no. 11, pages 1437-1446			
		Halm et al., "A phase II study of pegylated liposomal doxorubicin for treatment of advanced hepatocellular carcinoma," Ann. Oncol., 2000, 11(1):113-114			
		Hoekman et al., "A phase I/II study of dose-escalated docetaxel given two weekly in combination with a fixed dose of G-CSF," European Journal of Cancer, vol. 37, page S76, Abstract 270, October 22, 2001			

/Chris Simmons/

05/17/2009

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/575,132
(Use as many sheets as necessary)				Filing Date	July 7, 2006
				First Named Inventor	Sarah Donald
				Art Unit	1612
				Examiner Name	Chris E. Simmons
Sheet	3	of	3	Attorney Docket Number	13566.105014

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
		Horstmann et al., "Risks and Benefits of Phase I Oncology Trials, 1991 through 2002," New England Journal of Medicine, vol. 352, pages 895-904; March 3, 2005			
		Lau et al., "A Phase I and Pharmacokinetic Study of Ecteinascidin-743 (Yondelis) in Children with Refractory Solid Tumors." Clinical Cancer Research, vol. 11, pp. 672-677, Jan. 15, 2005			
		PR Newswire, PR Newswire, October 14, 2001, 4 pages			
		Puchalski et al., "Pharmacokinetics of Ecteinascidin 743 Administered as a 24-h Continuous Intravenous Infusion to Adult Patients with Soft Tissue Sarcomas associations with Clinical Characteristics, Pathophysiological Variables and Toxicity," Cancer Chemotherapy and Pharmacology, 2002, vol. 50, no. 4, pages 309-319			
		Pato-Lobo 2002 "Doxorubicin," entries 86-056 through 86-062, 2002 not in English			
		Sarosy et al., "Phase I Study of α2-interferon plus Doxorubicin in Patients with Solid Tumors," Cancer Research, vol. 46, pp. 5368-5371, 1986			
		Schwartzmann G. et al., "Marine Organisms as a Source of New Anticancer Agents," The Lancet Oncology, 2001, vol. 2, no. 4, pages 221-225			
		Twelves et al., "Phase I and pharmacokinetic study of YondelisTM (Ecteinascidin-743; ET-743) administered as an infusion over 1 h or 3 h every 21 days in patients with solid tumours," European Journal of Cancer, vol. 39, p. 1842-1851, 2003; available online August 14, 2003			
		Wollina, "Multicenter study of pegylated liposomal doxorubicin in patients with cutaneous T-cell lymphoma," Cancer 2003, 1:98(5):993-1001, published online July 24, 2003			

Examiner Signature	/Chris Simmons/	Date Considered	05/17/2009
--------------------	-----------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.